Claims

1. An assay method for the detection of potential for CVD or propensity to CVD in a human or non-human animal subject, said method comprising assessing the concentration of calprotectin in a calprotectin-containing sample taken from said subject.

2. A method as claimed in claim 1 wherein said sample is a body fluid selected from blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid.

3. A method as claimed in claim 1 or claim 2 wherein said sample is blood.

4. A method as claimed in any one of claims 1 to 3 wherein said sample is serum or plasma.

5. A method as claimed in claim 3 or claim 4 wherein a threshold calprotectin concentration above which said assay is indicative of potential for CVD or propensity to CVD is 0.45 mg/L.

6. A method as claimed in any one of claims 1 to 5 additionally comprising assessing the concentration of a second marker for CVD in said sample.

7. A method as claimed in claim 6 wherein said second marker is C-reactive protein.

8. A method as claimed in any one of claims 1 to 7 wherein said CVD is acute myocardial infarction.

9. A method as claimed in any one of claims 1 to 8 wherein said concentration of calprotectin is assessed by turbidimetry.

10. An assay kit for use in a method according to any one of claims 1 to 9, said kit comprising reagents and instructions for the performance of the assay method and for the interpretation of the results.

11. A kit as claimed in claim 10 further comprising calprotectin-containing reference samples.

12. A kit as claimed in claim 10 or claim 11 further comprising a detector.

13. A kit as claimed in any one of claims 10 to 12 further comprising C-reactive protein-containing reference samples.

14. An assay method for the determination of calprotectin in a calprotectin-containing body fluid, said method comprising the steps of:

(a) obtaining a calprotectin-containing liquid sample of, or derived from, said fluid;

(b) contacting said sample of said body fluid with a nanoparticle-bound anti-calprotectin antibody or antibody fragment, to bind said calprotectin; and

(c) assessing the calprotectin content by turbidimetry,

wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 65-140 nm.

15. A method as claimed in claim 14 wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 75-120 nm.

16. A method as claimed in claim 14 or claim 15 wherein said nanoparticles are substantially all of the same size (e.g. monodisperse).

17. A method as claimed in any one of claims 14 to 16

wherein an opacity enhancer is added in between steps (b) and (c).

18. A method as claimed in any one of claims 14 to 17 wherein said body fluid is selected from blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid.

19. A method as claimed in any one of claims 14 to 18 performed as an automated assay.

20. A kit for use as a diagnostic assay according to any one of claims 14 to 18 comprising:

one or more anti-calprotectin antibodies or antibody fragments immobilised on nanoparticles.

21. A kit as claimed in claim 20 further comprising a calprotectin solution of known concentration or a set of such solutions having a range of calprotectin concentrations.

22. A kit as claimed in claim 20 or claim 21 further comprising a light transmitting vessel.

23. A kit as claimed in any one of claims 20 to 22 further comprising an opacification enhancer.

24. A kit as claimed in any one of claims 20 to 23 further comprising a detector.

25. An automated apparatus to receive a calprotectin-containing body fluid sample, apply the anti-calprotectin antibody or antibody fragment immobilised on nanoparticles, optionally apply an opacification enhancer, and assess calprotectin content.

26. A method of diagnosis of a disease comprising the method as claimed in any one of claims 14 to 19 followed by comparison of said calprotectin content with a predetermined threshold value wherein said disease is selected from rheumatic diseases, Sjøgrens syndrome, intraocular inflammatory conditions, cystic fibrosis, acute and chronic lung disease, lung carcinoma, pulmonary cancers, colorectal cancer, inflammatory bowel disease, gastric cancer, colorectal adenoma or cancer, Chrohn's disease, ulcerative colitis, gastrointestinal mucosal inflammation, urinary stones, alcoholic liver disease, oral inflammatory mucosal disease, CNS inflammatory disease, HIV infection, secondary CNS infections in HIV infected patients, urinary tract infections, cystitis, pyelonephritis, endogenous posterior uveitis, haematological conditions, febrile conditions (infectious and non-infectious), CVD, acute myocardial infarction and apheresis.

27. A method of diagnosis as claimed in claim 26 wherein said disease is CVD.